REMARKS

I. THE REJECTION UNDER 35 U.S.C. § 102

The Office Action maintains the rejection of claims 1-5, 8, 9, 11 and 13-16 as being anticipated by Walker et al., J. Neuropathol. Exp. Neurol., 377-383 (1994); WO0162801; and Naslund et al. Applicants respectfully traverse the rejection.

The claimed invention is directed to a monoclonal antibody that specifically recognizes Aβ11-x peptides. The specification discloses:

> [0001] This invention relates to antibodies, including specified portions or variants, **specific for at least the human Amyloid-β--11 N-terminal site, i.e. Aβ11-x peptides**.
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> ...
>
> [0006] Recently, it was demonstrated that BACE-1 is the major β-secretase required for cleavage of APP at position +1 and that overexpression of BACE-1 results in an additional cleavage at the +11 site of the Aβ, generating shorter Aβ11-40 and Aβ11-42 fragments, hereinafter also referred to as the Aβ11-x peptides. These Aβ peptides have been detected in conditioned medium of primary rat neuronal cell cultures and mouse N2a cells, suggesting that they are normal APP cleavage products generated in neurons (3, 4, 5). Significantly, these shorter Aβ fragments have also been identified as major species in AD brains and normal aging brains by biochemical analysis (6) as well as in Down syndrome brains with AD pathology by immunohistochemistry studies (7). This event calls for a re-evaluation of the role of Aβ11-40/42 in the pathogenesis of Alzheimer's disease, especially in view of the fact that Aβ species beginning at Glu11 prove to be more insoluble than those beginning at position 1 of Aβ.
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> ...
>
> [0009] Specific assays for Aβ11-x detection should be capable of detecting A11-x in fluid samples at very low concentrations in a reproducible and consistent manner as well as distinguishing between Aβ11-x peptides and other fragments of APP, which may be present in the sample.

As discussed in the response filed on July 14, 2006, none of the references cited disclose an antibody that is specific for the Aβ11-x peptides, i.e., peptide fragments wherein cleavage occurs at 11-N terminal site, as defined in the present specification.

Reconsideration and withdrawal of the rejection of claims 1-5, 8-11 and 13-16 under 35 U.S.C. § 102 are respectfully requested.

II. THE SPECIFICATION

The Office Action objects to the specification as containing informalities. In response, Applicants submit that the amendment to the specification obviates any basis for the objection thereto. Reconsideration and withdrawal of the objection to the specification are respectfully requested.

III. THE OBJECTION TO CLAIMS 6 AND 7

The Office Action objects to claims 6 and 7 as containing informalities. In response, Applicants submit that the amendment to claims 6 and 7 obviates any basis for the objection thereto. Reconsideration and withdrawal of the objection to claims 6 and 7 are respectfully requested.

IV. THE REJECTION OF CLAIMS 13 AND 14 UNDER 35 U.S.C. §§ 101 AND 112

The Office Action rejects claims 13 and 14 under 35 U.S.C. § 101 and 35 U.S.C. § 112. In response, Applicants submit that the cancellation of claim 13 and the amendment to claim 14 obviate any basis for the rejection thereof under 35 U.S.C. § 101 and 35 U.S.C. § 112. Reconsideration and withdrawal of the rejection of claims 13 and 14 under 35 U.S.C. § 101 and 35 U.S.C. § 112 are respectfully requested.

V. THE REJECTION OF CLAIMS 14 AND 16 UNDER 35 U.S.C. § 112, 1st ¶

The Office Action rejects claims 14 and 16 under 35 U.S.C. § 112, first paragraph. In particular, the Office Action asserts that the specification does not enable using antibodies that specifically bind to Aβ11-χ peptides to diagnose all amyloid-related diseases.

In response, Applicants submit that the amendment to claims 14 and 16 obviates any basis for the rejection thereto under 35 U.S.C. § 112, first paragraph. Reconsideration and withdrawal of the rejection of claims 14 and 16 under 35 U.S.C. § 112, first paragraph, are respectfully requested.

VI. THE REJECTION OF CLAIM 16 UNDER 35 U.S.C. § 112, 2nd ¶

The Office Action rejects claim 16 under 35 U.S.C. § 112, second paragraph. In particular, the Office Action asserts that the term "carrier means" is indefinite.

In response, Applicants submit that the amendment to claim 16 obviates any basis for the rejection thereto under 35 U.S.C. § 112, second paragraph. Reconsideration and withdrawal of the rejection of claim 16 under 35 U.S.C. § 112, second paragraph, are respectfully requested.

VII. THE REJECTIONS OF CLAIMS 1, 2, 5, 8 AND 14-16 UNDER 35 U.S.C. § 102

The Office Action rejects claims 1, 2, 5, 8 and 14-16 under 35 U.S.C. § 102 as being anticipated by Solomon et al., Proc. Natl. Acad. Sci. USA, 93:452-455 (1996) ("Solomon"). In particular, the Office Action asserts that the antibodies raised against amino acids 1-28 and 8-17 of Aβ disclosed in Solomon would inherently recognize Aβ11-χ because the amino acid sequence of the immunogens are encompassed within these sequences.

The Office Action rejects claims 1, 2, 5, 8 and 14-16 under 35 U.S.C. § 102 as being anticipated by Huse et al., J. Biol. Chem., 277"16278-16284 (2002) ("Huse"). In particular, the Office Action asserts that Huse discloses (1) BNT77, a monoclonal antibody raised against amino acids 11-16 of Aβ; (2) 4G8, a monoclonal antibody that can detect Aβ1-40, Aβ11-40, Aβ1-34 and Aβ11-34; and (3) a method of detecting Aβ11-40/11-42 in Alzheimer's brains.

As discussed above, the claimed invention is directed to a monoclonal antibody that specifically recognizes *Aβ11-x peptides*. Solomon and Huse et al. do not disclose or suggest antibodies specific for an antibody that is specific for the Aβ11-x peptides as disclosed in the present specification.

Reconsideration and withdrawal of the rejection of claims 1, 2, 5, 8 and 14-16 under 35 U.S.C. § 102 are respectfully requested.

VIII. THE REJECTION OF CLAIMS 1-5, 8, 9, 11 AND 13-16 UNDER 35 U.S.C. § 103

The Office Action rejects claims 1-5, 8, 9, 11 and 13-16 under 35 U.S.C. § 103 as being obvious over Huse in view of Walker et al., J. Neuropathol. Exp. Neurol., 53:377-383 (1994), and WO0162801. In particular, the Office Action asserts that it would have been obvious for one skilled in the art to use an antibody raised against Aβ11-16 or use antibody that can recognize Aβ11-χ to detect Aβ11-χ in Alzheimer's disease because the level of Aβ11-40/42 has been shown increased in Alzheimer's patients.

For the reasons discussed above, the cited references do not disclose or suggest antibodies specific for the Aβ11-x peptides as defined in the present specification.

Reconsideration and withdrawal of the rejection of claims 1-5, 8, 9, 11 and 13-16 under 35 U.S.C. § 103 are respectfully requested.

IX. THE INDICATION OF ALLOWABLE SUBJECT MATTER

Applicants greatly appreciate the indication that claim 7 is allowed and that claim 6 is allowable if rewritten in independent form.

X. CONCLUSION

Early consideration and prompt allowance of the claims are respectfully requested. Should the Office require anything further, it is invited to contact Applicants' representative at the telephone number below.

Respectfully submitted,

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